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| 09/806,925      | 06/20/2001  | Seiichi Araki        | MTSU-1001US         | 7925             |

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EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/22/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,925

Applicant(s)

ARAKI ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 122, 124-137 and 153-167 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 122, 124-137 and 153-167 is/are rejected.
- 7) ☒ Claim(s) 153-167 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's amendment and request for continued prosecution (CPA) filed January 30, 2003, has been received and entered into the case.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 61 – 75 been renumbered 153 – 167.

#### ***Claim Objections***

1. Claims 153 – 167 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 122 and 124 – 137.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 124, 126, 154, and 156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 124 and 154 are drawn to a method for preventing or remedying infection, however are rendered vague and indefinite because it is unclear if the extract is a fraction treated with a fixed carrier or with column chromatography.

Claims 126 and 156 are confusing for reciting "out of fractions" because it is unclear which is the preferred, or required, fraction.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 122 and 153 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US 5965616).

Applicant claims a method for preventing or remedying an infection comprising administering a sugar cane derived extract, wherein the infections is bacterial, viral or fungal.

Wang teaches a method for treating skin conditions, the method comprising administering to a mammal an alpha hydroxyacid from a sugar cane derived acid (or a sugar cane derived extract) (abstract, claim 14).

Although Wang does not teach the method for preventing or remedying infection, the method steps are the same. Moreover, by practicing the methods of Wang, one would inherently be preventing infection. Therefore the reference anticipates the claimed subject matter.

6. Claims 122, 124 – 128, 130, 133 – 137, 153 – 158, 160 and 163 – 167 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawai et al. (EP 0943343 A1).

Applicant claims a method for preventing or remedying an infection comprising administering a sugar cane derived extract, wherein the infections is bacterial, viral or fungal. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, the extract is obtained by passing sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. The extract is a fraction which absorbs light at a wavelength of 420 nm, separated from other fractions obtained by column chromatography using an ion exchange resin, a cation exchange resin, a strongly acidic, or gel resin. The extract is obtained by extracting bagasse with water, hydrophilic solvent or mixtures thereof wherein the solvent is ethanol, or a mixture of ethanol and water at 60% or less ethanol, and 40% or more water. Finally, the extract is administered as food or animal feed.

Kawai teaches methods wherein sugar cane extracts are administered to subjects (human, dogs) (examples 4, 5). Specifically, the sugar cane extracts are obtained by a method wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted with water, methanol, ethanol or mixes

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thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). Specific examples of such medicines include food and drinks to patients to improve sanitary conditions (0032).

Although Kawai does not teach the method for preventing or remedying infection, the method steps are the same. Moreover, by practicing the methods of Kawai, one would inherently be preventing infection. In addition, although Kawai does not specifically teach the extract absorbs light at a wavelength of 420 nm, the methods of obtaining the extracts are the same. As such it would appear that the extract of Kawai would also intrinsically absorb light at the same wavelength. It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 122, 124 – 137 and 153 – 167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai in view of Saska (US 5443650), Agar et al. (US 5788812), Brewer (US 5454952) and Kearney (US 5102553).

Applicant claims a method for preventing or remedying an infection comprising administering a sugar cane derived extract, wherein the infections is bacterial, viral or fungal. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, the extract is obtained by passing sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. The extract is a fraction which absorbs light at a wavelength of 420 nm, separated from other fractions obtained by column chromatography using an ion exchange resin, a cation exchange resin, a strongly acidic cation or the sodium or potassium form, or gel resin. The ion exchange is carried out in a pseudo

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moving bed continuous separation, and the fraction is further treated with electrodialysis. The extract is obtained by extracting bagasse with water, hydrophilic solvent or mixtures thereof wherein the solvent is ethanol, or a mixture of ethanol and water at 60% or less ethanol, and 40% or more water. Finally, the extract is administered as food or animal feed.

Kawai teaches methods wherein sugar cane extracts are administered to subjects (human, dogs) (examples 4, 5). Specifically, the sugar cane extracts are obtained by a method wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted with water, methanol, ethanol or mixtures thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). Specific examples of such medicines include food and drinks to patients to improve sanitary conditions (0032).

Although Kawai does not teach the method for preventing or remedying infection, the method steps are the same. Moreover, by practicing the methods of Kawai, one would inherently be preventing infection. In addition, although Kawai does not specifically teach the extract absorbs light at a wavelength of 420 nm, the methods of obtaining the extracts are the same. As such it would appear that the extract of Kawai would also intrinsically absorb light at the same wavelength.

Kawai does not teach the method wherein a strongly acidic cation exchange resin is used of the sodium or potassium form, wherein the ion exchange is carried out in a moving bed

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continuous separation, or wherein the fraction is treated with electrodialysis. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to obtain extracts of sugar in these claimed methods, because they were routinely practiced in the art. In support, Saska teaches processes wherein sugar juice, or sugar derived molasses is treated with a strong cation exchange resin, in the form of sodium and/or potassium (abstract) and the eluted with water (col.2 line 21-29). Agar teaches methods for pulping plant materials such as bagasse (sugar cane extract), wherein extracts are recovered by treating the material with organic solvents (alcohol) (col.1 line 21-34, col.16 line 15-20), specifically with 60% ethanol and 40% water (col.4 line 24-26,35-50). Brewer teaches known methods for producing extracts of sugarcane using ion exchange, strongly acidic ion exchange resins (col.2 line 12-22), cations resins of the sodium form (col.2 line 33-39), and electrodialysis (col.3 line 8-10). Finally, Kearney teaches typical separation techniques of sugar extracts include ion exchange resins, continuous simulated moving bed systems (col.1 line 30-50). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practices to obtain the sugarcane extract of Kawai as claimed, since they well known procedures, as evidenced by the cited references.

It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper (MPEP 2113). Although the

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instant claims are drawn to a method, the method merely comprises administering such a product by process.

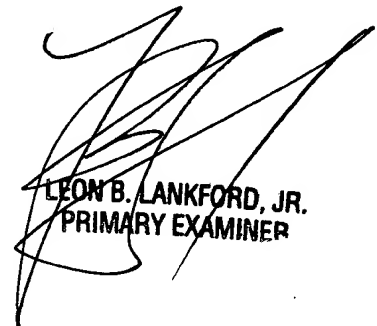
It is further noted that the instant claims read on eating sugar, since the extracts are obtained by the same methods practiced to obtain sugar (see cited references) and the methods are preventative in nature.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
April 17, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER